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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/734,592	10/22/1996	ANDREW GOODEARL	CNS-5250.27-	1576

7590 05/08/2003

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EXAMINER

GUCKER, STEPHEN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 05/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Art Unit: 1645

DETAILED ACTION

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 132 and 136-141 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 5,602,096.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the process steps of administering a ligand for the erb B2 receptor or a GGF are the same (*Ex parte Novitski*, 26 USPQ 1391). The instant process claims recite acetylcholine receptor synthesis stimulating activity. The sequences recited in the instant claims either encode an amino acid sequence comprising, or are an amino acid sequence comprising, SEQ ID NO: 170 recited in claim 2 of U.S. Patent No. 5,602,096 or its encoding sequence recited in claim 1 of the patent.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1645

4. Claims 132 and 139-140 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods reciting active domains of GGFs by SEQ ID NO, does not reasonably provide enablement for methods using GGFs that do not provide characterization other than encoded by a specific gene or binding to a receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. An EGF-like domain is not a fixed constant in chemical structure, but varies in amino acid composition and size from polypeptide to polypeptide. Although EGF-like domain sounds as if it could be a well-defined and easily recognized genus of amino acid sequences, it is not because EGF itself does not have an EGF-like domain as taught by the disclosure because EGF is ineffective as a GGF. If EGF is useless as a standard to compare EGF-like domains, the method claims reciting the use of chemical products are limited not by the chemical structure of those products but only by the function of said chemical products. Because of this unlimited variability in actual chemical structure and size of the EGF-like domain in the genus of polypeptides comprising EGF-like domains, Applicant's claims encompass methods using any polypeptide, regardless of actual structure that functions as if it had an EGF-like domain by lieu of the fact that it stimulates acetylcholine receptor synthesis. The instant claims encompass the use of all manner of polypeptides with an infinite variety of sequences, sizes, structures, etc. as long as those polypeptides possess the desired property of stimulating ACh receptor synthesis (behaving like a GGF). The limitation of being encoded by a gene is also not a chemical or structural limitation

Serial Number: 08/734,592

4

Art Unit: 1645

because any gene, many genes, or all genes meet the limitations of the claim as long as they possess the recited function of encoding a GGF ligand, a ligand being any chemical that functionally binds to the p185 erb B2 receptor. Because of the preceding reasons, the specification does not adequately describe or give sufficient guidance or examples to enable the broad scope (limited only by function, not structure) of the claims. It is not predictable which of an infinite variety of polypeptides meet the limitations of the claims without testing each and every one.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Thursday from 0730 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stephen Gucker

July 19, 1999



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